510(k) Summary

The assigned 510(k) number is: K070835

This summary of the 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

JUN - 4 2007

1.	Submitter name, address, contact	Olympus Life and Material Science Europa GmbH Lismeehan, O'Callaghan's Mills Co. Clare, Ireland	
		U.S. Telephone: U.S. Fax: Telephone:	469-230-0959 972-317-7861 011-353-65-683-1100
		Contact Person:	Stephanie G. Schwartz
		Date Prepared:	March 25, 2007
2.	Device name	Proprietary Name:	Olympus CK-MB Reagent (OSR6x155)
		Common Name:	CK-MB Reagent
		Classification Name:	Colorimetric Method, CPK or Isoenzymes test system.
3.	Predicate device	Reagent:	Olympus OSR6X53 CK-MB method Submitted (K971817)
4.	Device description	In this Olympus procedure: • The R1 reagent antibody binds to the M subunit of CK in the serum sample. • The B subunit of the enzyme acts on the substrate present in the R2 reagent. • CK reversibly catalyzes the transfer of a phosphate group from creatine phosphate to ADP to give creatine and ATP. • The ATP is used to produce glucose-6-phosphate and ADP, catalyzed by hexokinase (HK) which requires magnesium ions for maximum activity. • The glucose-6-phosphate is oxidized by the action of the enzyme G6P-DH with simultaneous reduction of the coenzyme NADP to give NADPH and 6-phosphogluconate. • The rate of increase of absorbance at 340/660 nm due to the formation of NADPH is directly proportional to the activity of CK-MB in the sample.	
5.	Intended use	System reagent for the quantitative determination of Creatine Kinase-MB isoenzyme in human serum and plasma on Olympus analyzers.	

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6. The following Tables compare the new Olympus CK-MB (OSR6x155) reagent with the current Olympus CK-MB (OSR6x53) reagent.

Similarities		
Item	Olympus CK-MB (OSR6x155) reagent	Predicate System
Intended Use	System reagent for the quantitative determination of Creatine Kinase-MB isoenzyme in human serum and plasma on Olympus analyzers.	System reagent for the quantitative determination of Creatine Kinase-MB isoenzyme in human serum and plasma on Olympus analyzers.
Instrument required	Olympus AU400/400[e], 600/640/640[e] and 2700/5400	Same
Measurement	Quantitative	Same
Specimen Type	Serum and heparinized plasma	Same
Assay Methodology	Isoenzymes	Same
Antibody	Antibody to CK-M subunit	Same
Calibration	Procedure is based upon a theoretical extinction coefficient.	Same
Expected Values	1 – 10 U/L	Same

Differences		
Item	Olympus CK-MB (OSR6x155) reagent	Predicate System
Traceability	This Olympus CK procedure is a modification of the IFCC method	This Olympus CK procedure is a modification of the Szasz method
Reagent storage form	Liquid On –board storage	Reconstituted On –board storage
Reagent Handling	R1: Mix R1-2 into R1-1 before placing on instrument. R2 Ready for use	R1: Dissolve the contents of one R1 Lyo completely with the contents of one bottle of R1 Buffer. R2: Dissolve the contents of one R2 Lyo completely with the contents of one bottle of R2 Buffer
Reagent On Board Stability	Opened reagents are stable for 30 days when stored in the refrigerated compartment of the analyzer.	Reconstituted reagents are stable for 5 days when stored in the refrigerated compartment of the analyzer.
Antibody	Polyclonal anti CK-M goat antibody	Polyclonal anti CK-M sheep antibody
Calibration	Calibration of this CK-MB procedure is based upon the theoretical extinction coefficient for NADPH, which has a molar absorptivity of 6300 at 340/660 nm.	Calibration of this CK-MB procedure is based upon the theoretical extinction coefficient for NADP, which has a molar absorptivity of 4960 at 340/380 nm.

Performance Characteristics		
Item	Olympus CK-MB (OSR6x155) reagent	Predicate System
Precision	AU400/400[e] Sample Total CV% 1 4.26 2 1.31 3 1.10 AU600/640/640[e] Sample Total CV% 1 5.05	AU400/400[e] Sample Total CV% 1 2.85 2 0.65 3 0.52 AU600/640/640[e] Sample Total CV% 1 9.12

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	2 1.15 3 0.90 AU2700/5400 Sample Total CV% 1 3.50 2 1.13 3 1.21	2 1.62 3 0.73 AU2700/5400 Sample Total CV% 1 5.59 2 3.54 3 3.76
Assay Range	10 to 2000 U/L	10 to 2000 U/L
Sensitivity	Typical change in absorbance per minute for 1 U/L of CK-MB is approximately 0.12 mAbsorbance	Typical change in absorbance per minute for 1 U/L of CK-MB is approximately 0.08 mAbsorbance
Method Comparison (Linear Regression)	Intercept 2.207 Slope 1.061 R^2 1.000 Range 12-1860 U/L	Intercept 2.700 Slope 0.965 R^2 1.000 Range 2-1881 U/L
Interfering Substances	AU600/640/640[e] Bilirubin: Interference less than 10% up to 40 mg/dL Bilirubin Lipemia: Interference less than 15% up to 900 mg/dL Intralipid AU400/400[e] Bilirubin: Interference less than 10% up to 40 mg/dL Bilirubin Lipemia: Interference less than 10% up to 900 mg/dL Intralipid AU2700/5400 Bilirubin: Interference less than 6% up to 40 mg/dL Bilirubin Lipemia: Interference less than 20% up to 900 mg/dL Intralipid	AU600/640/640[e] Bilirubin: Interference less than 3% up to 40 mg/dL Bilirubin Lipemia: Interference less than 10% up to 200 mg/dL Intralipid AU400/400[e] Bilirubin: Interference less than 3% up to 40 mg/dL Bilirubin Lipemia: Interference less than 3% up to 1000 mg/dL Intralipid AU2700/5400 Bilirubin: Interference less than 10% up to 24 mg/dL Bilirubin Lipemia: Interference less than 6% up to 1000 mg/dL Intralipid

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Olympus Life & Material Science
Europa GMBH (Irish Branch)
c/o Ms. Stephanie Schwartz
Regulatory Affairs/Quality Assurance Manager
Lismeehan, O'Callaghan's Mills, CO.
Clare, Ireland

JUN - 4 2007

Re: k070835
Trade/Device Name: Olympus CK-MB Reagent
Regulation Number: 21 CFR 862.1215
Regulation Name: Creatine phosphokinase/creatine kinase or isoenzymes test system
Regulatory Class: Class II
Product Code: JHY
Dated: March 24, 2007
Received: March 27, 2007

Dear Ms. Schwartz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k070835

Device Name: Olympus CK-MB Reagent

Indications For Use:

System reagent for the quantitative determination of Creatine Kinase-MB isoenzyme in human serum and heparinized plasma on OLYMPUS analyzers

Measurements of Creatine Kinase are used in the diagnosis and treatment of myocardial infarction and muscle diseases such as progressive, Duchenne-type muscular dystrophy.

Prescription Use ____X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

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